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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/636,033	08/07/2003	Oliver William Hardwicke Davies	DDI-0010-USA-CON	1033
27777	7590	04/07/2005	EXAMINER	
PHILIP S. JOHNSON			OLSEN, KAJ K	
JOHNSON & JOHNSON			ART UNIT	
ONE JOHNSON & JOHNSON PLAZA			PAPER NUMBER	
NEW BRUNSWICK, NJ 08933-7003			1753	

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/636,033

Applicant(s)

DAVIES ET AL.

Examiner

Kaj K. Olsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 29-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8-7-03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Specification

1. The title of the invention does not reflect the current claimed invention. The examiner recommends the title be changed to --Continuous Web of Electrochemical Sensors--.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 29-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Uenoyama et al (USP 6,125,292).
4. With respect to claim 29, Uenoyama discloses a plurality of electrochemical sensors being adapted for the detection of blood. Said plurality comprising a plurality of first and second electrodes (2, 3) screen printed as an array on a continuous sheet of substrate. See fig. 5A and 6A-C and col. 4, lines 48-56. Uenoyama further discloses a reagent layer printed over the various electrodes followed by a sealing layer 5 positioned over the reagent layer and the electrodes to form a sample receiving chamber. See fig. 5B and col. 4, line 54 through col. 5, line 9. With respect to this plurality of sensors being a “continuous web”, the applicant appears to utilize this term for any substrate device composed of a plurality of sensors. Because Uenoyama teaches the use of such a structure (see fig. 3A-C and col. 6, lines 6-38), Uenoyama meets the definition of “continuous web” giving the claim language its broadest reasonable

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interpretation. With respect to the array being “linear”, see leads 2a and 3a in fig. 6C and col. 6, lines 25-30. With respect to the substrate being “flexible” all the various materials specified in col. 4, lines 30-36 have some inherent degree of flexibility. Absent an explicit definition of the degree of flexibility desired, Uenoyama meets this limitation. With respect to the reagent being screen printed, the determination of patentability for the claim is based on the product itself.

Because the product of the claim is identical to the invention of Uenoyama the process from which it was made is the same as or obvious over the process utilized by Uenoyama (see *In re Thorpe*, 777 F.2d 695, 698).

5. With respect to claim 30, see col. 5, lines 6 and 7.
6. With respect to claims 31 and 32, see col. 5, lines 13-15.
7. With respect to claim 33, see col. 4, lines 48-52.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 29-33 are rejected in the alternative under 35 U.S.C. 103(a) as being unpatentable over Uenoyama in view of Diebold et al (USP 5,437,999) and/or WO 98/43075 (hereafter "WO '075").

11. Uenoyama set forth all the limitations of the claims, but did not explicitly refer to items like "continuous web" or "flexible substrate material" or the use of screen printing of the reagent. However, the absence of these terms or processes of making did not prevent Uenoyama from anticipated the claimed invention (see above). However, even if the examiner were to interpret these various limitations as reading away from the plurality of sensors of Uenoyama, these limitations would still have been obvious over Uenoyama in view of Diebold and/or WO '075. In particular, Diebold teaches that a plurality of sensors can be constructed on a continuous web of flexible substrate material. See col. 6, lines 35-60. Diebold also suggests screen-printing the reagent layer. See col. 10, lines 14-34. WO '075 discloses manufacturing a plurality of sensors via continuous flexible web of substrate material. See p. 10, line 30 through p. 11, line 23. WO '075 also discloses that screen-printing of electrode layers is old in the art. See p. 1, lines 7-30. Both of these manufacturing processes provide a means for constructing a plurality of sensors in a rapid manner (see WO '075, p. 2, lines 4-7) and it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teachings of Diebold and/or WO '075 for the plurality of sensors of Uenoyama so that the sensors can be rapidly manufactured.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Thursday from 5:30 A.M. to 3:00 P.M. and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AU 1753
March 31, 2005


KAJ K. OLSEN
PRIMARY EXAMINER